

APR 14 2000

REMARKS

TECHNICAL CENTER 1600/2000

Favorable reconsideration in view of the herewith presented amendment and remarks is respectfully requested.

Applicants have amended the title of the invention to more clearly point out the subject matter of Applicants' invention.

Claim 38 was objected to under 37 C.F.R. 1.75(c) as being in improper form. Applicants have amended claim 38 and added claim 39 to correct the improper form noted by the Examiner on page 2 of the Office Action. Accordingly, Applicants respectively request reconsideration and withdrawal of the rejection of claim 38 under 37 C.F.R. 1.75(c).

Claims 24-38 were rejected under 35 U.S.C. § 112, ¶2 as being indefinite. In particular, the Examiner rejected Claims 24, 25, 32, and 33 as indefinite because the Examiner alleges that the term "enhancing" is a relative term that renders the claim indefinite.

Applicants respectively traverse this rejection.

It is urged that Applicants' disclosure does provide a standard for ascertaining the meaning of the term "enhancing". Applicants' invention is directed to an agent that enhances athletic endurance. The term "endurance" refers to the length of time one can engage in an athletic activity. An agent that enhances endurance will enable a subject to engage in an activity for a longer period of time until tiring than the subject would otherwise be able to do without having administered the agent. The term "enhancing" is synonymous with the term "increasing". Applicants' disclosure states that a subject's athletic endurance is associated with that subject's maximum oxygen

uptake capacity, and Applicants disclose test results indicating that administering Applicants' invention to a subject over a period of time increased that subject's maximum oxygen uptake capacity. Therefore, administering the agent of Applicants' invention to a test subject enables that subject to endure an activity longer than that subject would otherwise be to do so. Thus, Applicants' disclosure does provide a standard for ascertaining the meaning of the term "enhancing".

Therefore, Applicants urge that claims 24, 25, and amended claims 32, and 33 are definite within the meaning of 35 U.S.C. § 112, ¶2. Claims 26-31 are dependent on claims 24 or 25, and amended claims 34-38 are dependent on amended claims 32 or 33, and are thus definite for the same reasons as claims 24, 25, 32, and 33. Reconsideration and withdrawal of this rejection of claims 24-38 is respectfully requested.

Claims 32-35 and 37-38 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 3,764,692 (Lowenstein).

Applicants respectfully traverse this rejection.

In order for a prior art reference to anticipate under § 102, every element of the claimed invention must be disclosed either expressly or under the principles of inherency. Lowenstein's claim 7 claims a pharmaceutical composition for the treatment of obesity comprising a pharmaceutical carrier and a compound selected from a group that includes, *inter alia*, garcinia acid, the term by which Lowenstein refers to (-) hydroxycitric acid. Applicants, in claims 32 and 33, claims a method for enhancing exercise endurance comprising, *inter alia*, a food and (-) hydroxycitric acid. Lowenstein does not claim administering a food as part of his invention, and his disclosure indicates that his invention was intended to be administered by means of standard

pharmaceutical carriers, such as tablets, capsules, suppositories, liquid suspensions or liquid emulsions. (Lowenstein, col. 2, lines 34-38.) These carriers are not considered to be food, and administering the agent of Applicants invention by means of the food carriers listed in claim 38 is not inherent in Lowenstein's list of pharmaceutical carriers. (The Examiner actually refers to claim 23 on page 4 of the Office Action. Since claim 23 was canceled in the Amendment dated September 3, 1999, Applicants assume that the Examiner is referring to claim 38 instead.) Finally, Lowenstein does not even remotely teach enhancement of exercise endurance.

Thus, Applicants respectfully urge that claims 32-35 and 37-38, as amended, are not anticipated by Lowenstein and reconsideration and withdrawal of this rejection is respectfully requested..

Claims 32 and 34-36 were rejected under 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 3,764,692 (Lowenstein) in light of U.S. Patent No. 5,536,516 (Moffett, et al.).

Applicants respectfully traverse this rejection.

The Examiner alleges that even though Lowenstein does not teach the use of the specific foods listed in Applicants' claim 38, it would be obvious to use these food items to administer the (-)hydroxycitric acid instead of the pharmaceutical carriers disclosed in Lowenstein. (The Examiner actually refers to claim 23 on page 4 of the Office Action. Since claim 23 was canceled in the Amendment dated September 3, 1999, Applicants assume that the Examiner is referring to claim 38 instead.)

Applicants urge otherwise.

The use of pharmaceutical carriers with a medical agent enables a user to administer a precise, known dosage of that agent. The inclusion of medical agents with

food carriers is not taught by the use of pharmaceutical carriers because those skilled in the art recognize that food items are not acceptable pharmaceutical carriers. Thus, Applicants urge that it not obvious in light of Lowenstein to include a food carrier with the (-) hydroxycitric acid. Furthermore, Applicant's urge that Lowenstein's use of (-) hydroxycitric acid to treat obesity does not teach Applicants use of that compound to enhance exercise endurance, and, based on (-) hydroxycitric acid's known metabolic effects, it would not be obvious to use it for Applicants' purpose. Therefore, reconsideration and withdraw of this rejection of claim 32, as amended, is respectfully requested.

The Examiner also rejected claims 34-36, alleging that it would be obvious in light of Lowenstein to extract the (-)hydroxycitric acid from *G. cambogia*, and in light of Moffett to extract the (-)hydroxycitric acid from *G. indica* and *G. atroviridis*. Applicants urge, however, that by further limiting amended claim 32, claims 34-36, as amended, are allowable for at least the reasons that amended claim 32 is allowable, and respectfully request reconsideration and withdrawal of this rejection.

Claims 24-31 were rejected under 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 3,764,692 (Lowenstein) in light of U.S. Patent No. 5,536,516 (Moffett, et al.) and McCarty (45 Medical Hypotheses 247-54 (1995)).

Applicants respectfully traverse this rejection.

The Examiner concedes that Lowenstein and Moffett do not teach the use of (-)hydroxycitric acid for increasing athletic endurance. The Examiner alleges, however, that McCarty shows that (-)hydroxycitric acid can be administered to increase exercise endurance.

Applicants respectfully disagree with this interpretation of McCarty.

McCarty states that (-)hydroxycitric acid may serve to prolong aerobic exercise because of increasing gluconeogenesis. In particular, McCarty states that (-)hydroxycitric acid inhibits citrate lyase and promotes hepatic lipid oxidation, ketogenesis, and gluconeogenesis, resulting in the accumulation of glycogen in the liver. McCarty simply assumes without any experiments that this (-)hydroxycitric acid induced glycogen accumulation may enable intensified aerobic exercise.

McCarty's assumption is not supported by other scientific evidence. Dohm, et al., 55:3 J. App. Physiol. 830-33 (1983) suggests the opposite conclusion from McCarty, namely that the absence of glycogen, rather than the accumulation of glycogen, enhances athletic performance. Thus, those skilled in the art would judge McCarty's assumption to be wrong, and undue experimentation would be required to produce Applicants' invention based on the McCarty reference.

Indeed, Applicants refer to the intensive research required to produce what Applicants regarded as a surprising result, that (-)hydroxycitric acid of a practical amount showed an exercise endurance enhancing action. The Examiner's rejection herein is tantamount to the use of an "obvious to try" standard which has been found to be erroneous by the Court of Appeals for the Federal Circuit. It is urged that the correct standard is what the combination of the prior art references would have suggested to the skilled artisan. There must be a basis for the artisan to have a reasonable expectation of achieving the result found in the invention sought to be patented. Such is clearly not the case herein.

Thus, Applicants urge that claims 24-31 are not obvious in light of Lowenstein, Moffett, and McCarty, and respectfully request reconsideration and withdrawal of this rejection.

It is submitted that claims 24-38, as amended, and new claim 39 are in condition for allowance. Early and favorable action by the Examiner is earnestly solicited. If the Examiner believes that issues may be resolved by a telephone interview, the Examiner is respectfully urged to telephone the undersigned at (212) 848-1046. The undersigned may also be contacted by e-mail at erzucidlo@gj.com.

AUTHORIZATION

The Commissioner is hereby authorized to charge any additional fees which may be required for this amendment, or credit any overpayment to Deposit Account No. 07-1855.

Respectfully submitted,

Graham & James LLP

Date: April 5, 2000

By:



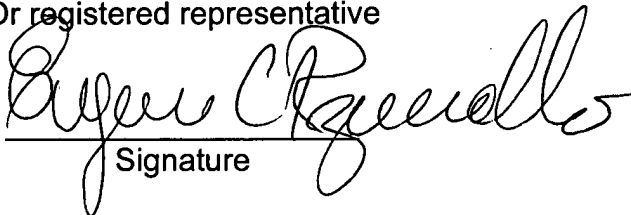
EUGENE C. RZUCIDLO
Attorney for Applicants
Registration No. 31,900

GRAHAM & JAMES LLP
885 Third Avenue, 22nd Floor
New York, NY 10022-4834
(212) 848-1000

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This is to certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to Assistant Commissioner for Patents, Washington, D.C. 20231, on April 5, 2000.

Eugene C. Rzucidlo
Name of applicant, assignee
Or registered representative


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April 5, 2000
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